VAMHCS RESEARCH SERVICE HOT TOPIC

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Update on Allowable Signatures for HIPAA Authorizations for Participants with Impaired Decision-Making Capacity

- VAMHCS has recently received clarification from VHA Office of Research Compliance and VHA Office of General Counsel that reverses the information disseminated in Hot Topic Vol. 6, No. 3 (2/13/12) on who may sign HIPAA authorizations on behalf of participants with impaired decision-making capacity (IDMC).

- **New Information**: In the State of Maryland, the following individuals may sign HIPAA authorizations on behalf of participants with IDMC (listed in order of priority):
  - Durable Power of Attorney (DPA) for Health Care,
  - legal guardian of an individual,
  - the executor of the estate of a deceased individual,
  - the patient's spouse,
  - an adult child (18 years or older) of the patient,
  - a parent of the patient,
  - adult sibling (18 years or older) of the patient,
  - an adult grandparent or grandchild (in that order of preference) of the patient (but no other relative, or
  - a close friend.

- **Revised VAMHCS HIPAA Authorization template**:
  - Removes the explanatory paragraph on the signature page that stated the restrictions on who could sign HIPAA authorizations for IDMC participants.
  - Adds some new prompts/suggestions to assist Investigators in completing the template (the prompts are for assistance only and do not change the substance of the form).
  - The new version is dated 04.08.2014 and replaces the 08.11.2011 version (version date is in the bottom right corner of the form).

- **Implementation**:
  - For **all new human research protocols**, beginning with its June 12, 2014 meeting, the VAMHCS R&D Committee (RDC) will require the new HIPAA template.
  - For **all currently active protocols:**
    - *If your research protocol(s) involve or may potentially involve IDMC participants* you must transition to the new HIPAA template with

your next protocol modification request. If you have not modified your protocol for other reasons by12/31/14, then submit a specific modification to transition to the new HIPAA template by 12/31/14.

- *If your research protocol(s) do not involve IDMC participants*, you do not need to take any action at this time.
- As always, be sure to check your CICERO protocol, your informed consent form, and any other applicable documents to be sure that they are all consistent with the revised HIPAA authorization.
- There is no requirement for current or past participants to sign the new HIPAA authorization *unless the IRB requires it.*

- **Access to the new template**:
  - A revised HIPAA authorization is attached and will be posted on the R&D Service website.
  - A "tutorial" version of the new HIPAA template is also attached and will also be located on the R&D Service website.
  - VAMHCS will work with the UM Human Research Protections Office to replace the template on the UM and CICERO sites.
  - Hot Topic Vol. 6, No. 3 will be archived and will no longer be posted on the R&D Service website. This Hot Topic will be posted on the R&D Service website.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

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